FEB - 5 2004 510K SUMMARY

K033451
1 of 2

Applicant's Name, Address, Telephone and Fax Numbers:
Universal Medical, Inc., 101 Ludlow Drive, Ewing, New Jersey 08638; phone-(609-671-1790); fax-(609-671-1765).

Contact Person:
Douglas M. Lurio, Esquire and Margaret Sherry Lurio, Esquire, Lurio & Associates, P.C., Suite 2340, One Commerce Square, 2005 Market Street, Philadelphia, PA 19103, phone-(215)665-9300; fax-(215)665-8582; email-Douglas M. Lurio, Esquire (doug@luriolaw.com); Margaret Sherry Lurio, Esquire (mslu@luriolaw.com).

Classification Name:
Telephone Electrocardiograph Transmitters and Receivers, 21 CFR 870.2920.

Common/Usual Name:
Hand held, portable, externally applied transtelephonic event recorders, which are intended for transtelephonic use.

Proprietary Name:
Heartrak Smart AT/Heartrak Smart^2.

Device Description and Intended Use:
Heartrak Smart AT/ Heartrak Smart ^{2} will be manufactured by Universal Medical, Inc. at its offices at 101 Ludlow Drive, Ewing, NJ 08638. Heartrak Smart AT/Heartrak Smart^2 is a patient-activated transtelephonic ECG loop memory monitor which records cardiac patients' symptoms. The patient calls the receiving center, hospital or physician's office from the patient's home. Heartrak Smart AT/Heartrak Smart^2 converts signals into audio tones which are transmitted over telephone lines. Heartrak Smart AT/Heartrak Smart^2 is a hand held, portable, externally applied device which is intended for transtelephonic use. Heartrak Smart AT/Heartrak Smart^2 does not deliver any energy, administer any drugs, or control a patient's life. Heartrak Smart AT/Heartrak Smart^2 is not a diagnostic tool and performs no diagnostic functions. There are no patient age limitations for Heartrak Smart AT/Heartrak Smart^2.

Establishment Registration Number:
No. 2248680

Classification:
In the Federal Registration notice of February 5, 1980, relative to Cardiovascular Devices, the FDA identified Telephone Electrocardiograph Transmitters and Receivers as a Class II

device.

Promotional Material:
Promotional literature and advertisements for the device have not yet been prepared.

Predicate Device:
Heartrak XL (K960499)

Substantial Equivalences:
The Heartrak Smart At/Heartrak Smart^2 is substantially equivalent to the predicate device. The intended use, materials, packaging, labeling, method of operation and manufacturing methods have been proven to be identical. The safety and effectiveness of these devices is substantially equivalent to the predicate device. There are no known contradictions for use of this type of device. All of the features in one or both of these devices present a non-significant risk to the user.

Address for Manufacturing Site:
Heartrak Smart AT/Heartrak Smart^2 will be manufactured by Universal Medical, Inc. at its offices at 101 Ludlow Drive, Ewing, New Jersey 08638.

Materials:
The materials used in the manufacture of the Heartrak Smart AT/Heartrak Smart^2 are identical to the materials used in the predicate device.

Technological Characteristics:
The device is technologically equivalent to the predicate device and other event recorders.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2004

Universal Medical, Inc.
c/o Ms. Margaret Sherry Lurio
Lurio and Associates, P.C.
2005 Market Street, Suite 2340
Philadelphia, PA 19103-7015

Re: K033451
Trade Name: Heartrak Smart AT/Heartrak Smart 2
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: January 14, 2003
Received: January 15, 2004

Dear Ms. Lurio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033451

Device Name: Heartrak Smart AT/ Heartrak Smart^2

Indications for Use:

Used as a supplement to Holter Monitoring to document infrequent/transient symptoms such as lightheadedness, chest discomfort, palpitations, pre-syncope and syncope events.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED:

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the Counter Use _____

(Optional Format 1-2-96)

Daniel R. Schmer

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510(K) Number K033451